UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MERCK EPROVA AG,

Plaintiff,

-vs.-

BROOKSTONE PHARMACEUTICALS, LLC a/k/a ACELLA PHARMACEUTICALS, LLC,

Defendant.

09 CV 9684 (RJS)(JCF)

JURY DEMAND

FIRST AMENDED COMPLAINT

Plaintiff Merck Eprova AG ("Merck" or "Plaintiff") files this Complaint against Defendant Brookstone Pharmaceuticals, LLC a/k/a Acella Pharmaceuticals, LLC ("Brookstone" or "Defendant") and in support thereof alleges as follows:

NATURE AND BASIS OF ACTION

1. This action arises out of Defendant's knowing and willful false and misleading advertising and promotion of its products. Defendant's actions constitute false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B); contributory false advertising in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B); federal unfair competition in violation of Section 43(a)(1)(A) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(A); unfair competition in violation of New York common law; deceptive trade practices in violation of N.Y. Gen. Bus. Law § 349(h); and false advertising in violation of N.Y. Gen. Bus. Law § 350(e)(3). Plaintiff seeks temporary, preliminary and permanent injunctive relief, actual damages, punitive damages, and recovery of Plaintiff's costs and reasonable attorneys' fees incurred in connection with this action.

PARTIES

2. Plaintiff Merck is a Swiss corporation with a principal place of business at Im Laternenacker 5, CH-8200 Schaffhausen, Switzerland.

3. Upon information and belief, Defendant Brookstone is a limited liability corporation organized under the laws of Georgia and having its principal place of business at 9005 Westside Parkway, Alpharetta, Georgia 30004.

4. Upon information and belief, Defendant Brookstone is also known as Acella Pharmaceuticals LLC and transacts business within this judicial district and elsewhere under both names.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338 because this case arises under the Lanham Act, 15 U.S.C. §§ 1051, *et seq.*

6. This Court has jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367 and the doctrine of supplemental jurisdiction.

7. This Court has personal jurisdiction over Brookstone because Brookstone transacts business within the State of New York, contracts to supply goods or services in the State of New York, has engaged in tortious acts within the State of New York, and has engaged in tortious acts outside the State of New York causing injury within the State. More specifically, Brookstone markets, promotes, advertises, offers for sale, sells, and/or distributes its products to customers including wholesalers, retailers, chains, distributors, mail order houses, independent pharmacies, managed care organizations, and/or others throughout the United States, including in the Southern District of New York. Brookstone has purposefully and voluntarily placed its products into the stream of commerce with the expectation that they will be purchased by consumers in the Southern District of New York. As such, Brookstone has established minimum contacts with the forum such that the exercise of jurisdiction over it would not offend traditional notions of fair play and substantial justice.

8. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) because a substantial part of the events and injury giving rise to Plaintiff's claims has and continues to occur in this district.

FACTUAL BACKGROUND

A. Merck and Its L-5-MTHF Product: METAFOLIN®

9. Merck Eprova is the Swiss affiliate of Merck KGaA and provides active pharmaceutical and dietary ingredients to the pharmaceutical and nutritional industry for use in clinical trials and commercial product applications. One such product is marketed in connection with famous and distinctive trademarks consisting in whole or in part of the term METAFOLIN® (the "METAFOLIN® Marks").

10. The METAFOLIN® Marks are owned by Merck KGaA. Merck Eprova has an exclusive license from Merck KGaA to use these METAFOLIN® Marks in the United States. Merck KGaA owns Trademark Registration Nos. 3001087 and 2526532 and U.S. Trademark Serial No. 77423655 in the United States Patent and Trademark Office for the METAFOLIN® Marks.

11. The METAFOLIN® Marks have been used by Merck and its customers in connection with the dietary ingredient (6S)-N-[4-[[(2-amino-1,4,5,6,7,8-hexahydro-5-methyl-4-oxo-6-pteridinyl)methyl]amino]benzoyl]-L-glutamic acid, calcium salt, also known as L-5-methyltetrahydrofolic acid, calcium salt, L-methylfolate, (6S)-5-MTHF or L-5-MTHF.

12. L-5-MTHF is a source of folate, an essential human vitamin of the B complex.

13. Merck filed a New Dietary Ingredient Notification with the United States Food and Drug Administration ("FDA") in 2001 for its dietary ingredient L-5-MTHF.

14. Merck supplies L-5-MTHF as a bulk substance. Merck's licensees/customers then use METAFOLIN® brand L-5-MTHF in various dietary supplements, medical foods, nutritional supplements, pregnancy vitamins, and food for special dietary use.

15. Merck began manufacturing and distributing its L-5-MTHF dietary ingredient in 2002. Since then, Merck and its customers have established a considerable market in the United States for the product marketed, distributed, imported, and sold.

16. One such Merck customer, Sciele Pharma, Inc. ("Sciele"), markets and sells the prescription prenatal vitamins PRENATE DHA® and PRENATE ELITE® that comprise METAFOLIN® among other nutritional substances.

17. PRENATE ELITE® is a multivitamin/multimineral nutritional supplement and PRENATE DHA® is a multivitamin/mineral/essential fatty acid nutritional supplement, which are indicated for use in improving the nutritional status of women throughout pregnancy and in the postnatal period for both lactating and nonlactating mothers. PRENATE ELITE® and PRENATE DHA® can also be beneficial in improving the nutritional status of women prior to conception.

18. By virtue of the benefits contributed by METAFOLIN®, PRENATE DHA® and PRENATE ELITE® have achieved success as prescription multivitamin/multimineral nutritional supplements.

19. Merck's METAFOLIN®, when present in PRENATE DHA® and PRENATE ELITE®, is critical to enhance the health of a consumer population with severe folate needs, and, in the case of pregnant women, to ensure the wellbeing of a woman's unborn child.

20. Another of Merck's customers, Pamlab LLC, markets and sells the prescription medical food METANX® that comprises METAFOLIN® among other nutritional substances.

21. METANX® is a prescription medical food for the dietary management of endothelial dysfunction in patients with diabetic peripheral neuropathy.

22. By virtue of the benefits contributed by METAFOLIN®, METANX® has achieved success as prescription medical food.

23. Merck's METAFOLIN®, when present in METANX®, is critical to enhance the health of a consumer population with specific nutritional needs.

24. Upon information and belief, Merck is the only importer, licensor, and primary distributor of L-5-MTHF in the United States, directly and through its licensees, that adheres to well-accepted industry specifications. Merck distributes, as well as, licenses METAFOLIN® brand L-5-MTHF to its customers.

25. The presence of the dietary ingredient L-5-MTHF is used by Merck's customers as a unique selling point. The unique benefits of L-5-MTHF come from, *inter alia*, the fact that it consists of a single diastereoisomer.

26. Many products occur as mixtures of two or more diastereoisomers.

27. The various diastereoisomers that are present in such mixtures can have radically different properties from one another. In some cases, one diastereoisomer can have a therapeutic effect, while another diastereoisomer is therapeutically ineffective. In the most severe instances, one diastereoisomer may be highly toxic while another diastereoisomer may have incredible pharmacological utility. Thus, there are often great benefits to providing patients and consumers with a product that contains only a single diastereoisomer as opposed to a diastereoisomeric mixture.

28. Diastereoisomers are distinguished from one another through naming conventions that reflect their different properties. One such naming convention uses a "D" in the name of the compound for one diastereoisomer and an "L" in the name of the compound to indicate a different diastereoisomer.

29. The product 5-methyltetrahydrofolic acid is a 1 to 1 mixture of two diastereoisomers, the "L-form" and the "D-form."

30. The L-form (*i.e.*, L-5-MTHF) is highly preferable to the D-form (*i.e.*, D-5-MTHF) because the L-form is the naturally occurring predominant form of folate found

in food and the human body. The L-form is the biologically active form of folate and has proven to have a high degree of bioavailability (the rate at which a drug or other substance is available at the targeted place in the body) in humans. In contrast, the D-form is an unnatural form of folate, from which humans are unable to benefit.

31. L-5-MTHF is the pure diastereoisomeric form of folate used by cells in the body. In humans, this particular compound is the predominant form of folate in circulation and transport into the tissues, and it is the only folate that can cross the blood-brain barrier.

32. While the D-form is inactive as a source of folate nutritional activity, scientific evidence raises concerns that this inactive folate is not inert with respect to its *in vivo* behavior. In fact, the presence of any appreciable amount of the D-5-MTHF diastereoisomer could compete with the uptake and activity of the L-5-MTHF diastereoisomer and therefore reduce the overall usability of the compound.

33. There is also scientific evidence that the unnatural D-form accumulates in the human body, raising concerns in the medical community.

34. Merck's L-5-MTHF complies with all applicable requirements for dietary ingredients established by the FDA and its product adheres to industry specifications for L-5-MTHF.

35. Over the years, Merck has spent many millions of dollars researching and developing its L-5-MTHF, and devotes significant financial resources each year to marketing its product.

36. Merck has conducted extensive clinical and laboratory trials and testing on its L-5-MTHF.

37. Merck receives substantial revenue from its L-5-MTHF dietary ingredient. Merck's customers similarly receive substantial revenue from their products using L-5-MTHF.

38. Merck is acclaimed worldwide for its novel drugs and therapeutic products.

39. Merck's products are some of the most well-known and well-respected medical and dietetic products worldwide.

40. Over the years, Merck has endeavored to expand and to build its trade name, trademarks and products.

41. Merck has over the years worked extremely hard to ensure that the quality of the Merck L-5-MTHF product is extraordinarily high and that this product is of the highest safety and efficacy. In particular, Merck has conducted countless experiments and tests to determine the safety and efficacy of its L-5-MTHF, and spent years and millions of dollars on research and development to discover and perfect the product.

B. Generics

42. Products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product.

43. A pharmacist presented with a doctor's prescription for a brand-name product may fill that prescription by dispensing the brand-name product prescribed or a true "generic" version of the brand-name product. This process is known as generic substitution.

44. A generic product is only therapeutically equivalent to a brand-name product if such products are, *inter alia*, pharmaceutical equivalents. Moreover, to be considered therapeutically equivalent to a brand-name product, tests establishing such equivalency must have been conducted on the generic product.

45. Products are considered to be pharmaceutical equivalents if they contain, among other things, the same ingredient(s), including the same active ingredient(s); they are of the same dosage form and route of administration; and they are identical in strength or concentration.

46. For pharmacists and other medical professionals, the requirement of therapeutic equivalence, including pharmaceutical equivalence, ensures that a generic product substituted for the prescribed brand-name product is truly interchangeable and will provide the patient with the treatment the doctor ordered. This is critical because the doctor, not the wholesaler, distributor or pharmacist, is responsible for making the appropriate treatment decisions and tracking the patient's progress.

47. State and federal law govern pharmacy practice, including generic product substitution. Most state and federal laws explicitly require that a substitute product be both pharmaceutically equivalent as well as bioequivalent, and hence "therapeutically" equivalent to the brand-name product prescribed.

48. Thus pharmacists and other medical professionals expect, and rely upon the representations of a manufacturer, that a product advertised, promoted and sold as a generic product will be therapeutically equivalent to the brand-name product.

C. Defendant's Unlawful Conduct

49. Brookstone is in no way affiliated with Merck or its related entities.

50. Upon information and belief, Brookstone is a pharmaceutical company that develops, manufactures, markets and sells what it calls "niche generic pharmaceuticals" or "specialty generic products."

51. Brookstone sells and distributes its products nationwide, including sale and distribution in New York State, in particular.

52. Upon information and belief, sometime in 2009, Brookstone saw an opportunity to exploit the reputation and success of various products comprising METAFOLIN®. Specifically, Brookstone engaged in the manufacture, distribution, marketing, sale and/or offer for sale of alleged generic versions of Sciele's PRENATE DHA® and PRENATE ELITE® and Pamlab's METANX®.

53. Upon information and belief, before November 12, 2009, Brookstone contacted national pharmaceutical databases and supplied those databases with information detailing and describing its "PNV-DHA Oral Capsule 27-0.6-0.4-300 MG product" ("PNV-DHA"), "PNV Oral Tablet 27-0.6-0.4 MG product" ("PNV") and its "Folast product" ("Folast") (collectively the "False Generics").

54. Upon information and belief, Brookstone requested that those databases list its PNV-DHA, PNV, and Folast products as being equivalent to, and therefore lawfully substitutable for, Sciele's PRENATE DHA®, and PRENATE ELITE® and Pamlab's METANX®, respectively.

55. Upon information and belief, national pharmaceutical databases accepted Brookstone's representations and listed Brookstone's False Generics with the corresponding branded products.

Falsely Labeled Products: PNV-DHA PNV, and Folast

56. Upon information and belief, Brookstone has made and continues to make false representations regarding its PNV-DHA, PNV, and Folast products.

57. Upon information and belief, through at least its label, product insert and marketing materials, Brookstone has represented that its PNV-DHA product uses the following dietary ingredients in the following amounts:

Vitamin C (ascorbic acid)	85 mg
Vitamin D3 (cholecalciferol)	200 IU
Vitamin E (d-alpha tocopherol acetate)	10 IU
Vitamin B6 (pyridoxine HCl)	25 mg
Folate	1 mg
(L-methylfolate as Xolafin™ 600 mcg)	
(folic acid, USP 400 mcg)	
Vitamin B12 (cyanocobalamin)	12 mcg
Calcium (calcium carbonate)	140 mg
Iron (ferrous fumarate)	27 mg
Magnesium (magnesium oxide)	45 mg
Docosahexaenoic Acid (DHA)	300 mg

58. Brookstone's PNV-DHA product does not use the ingredient L-methylfolate (*i.e.*, L-5-MTHF), but instead uses the ingredient D,L-5-MTHF (also called "5-MTHF").

59. Upon information and belief, through at least its label, product insert and marketing materials, Brookstone has represented that its PNV product uses the following dietary ingredients in the following amounts:

Vitamin A (100% as beta carotene)	2500IU
Vitamin C (ascorbic acid)	80 mg
Vitamin D3 (cholecalciferol)	400 IU
Vitamin E (d-alpha tocopherol acetate)	10 IU
Vitamin B1 (thiamine mononitrate)	3 mg
Vitamin B2 (riboflavin)	3.4 mg
Niacinamide	20 mg
Vitamin B6 (pyridoxine HCl)	20 mg
Folate	1 mg
(L-methylfolate as Xolafin™ 600 mcg)	
(folic acid, USP 400 mcg)	
Vitamin B12	12 mcg
Biotin	300 mcg
Pantothenic acid (calcium pantothenate)	6 mg
Calcium (calcium carbonate)	120 mg
Iron (ferrous fumarate)	27 mg
Magnesium (magnesium oxide)	30 mg
Zinc (Zinc Oxide)	15 mg
Copper (Copper Oxide)	2 mg

60. Brookstone's PNV product does not use the ingredient L-methylfolate (*i.e.*, L-5-MTHF), but instead uses the ingredient D,L-5-MTHF.

61. Upon information and belief, through at least its label, product insert and marketing materials, Brookstone has represented that its Folast product uses the following dietary ingredients in the following amounts:

L-methylfolate [6(S)-5-MTHF] (as Xolafin™)	2.8 mg
Pyridoxal 5'-phosphate	25 mg
Methylcobalamin	2 mg

62. Brookstone's Folast does not use the dietary ingredient L-methylfolate (*i.e.*, L-5-MTHF), but instead uses the dietary ingredient D,L-5-MTHF.

63. Upon information and belief, Brookstone has represented and continues to represent in labels and package inserts that the Xolafin™ folate ingredient is "L-methylfolate [6(S)-5-MTHF]" or "L-methylfolate." Moreover, the package insert for Folast represents that the L-methylfolate ingredient in this product is the "primary biologically active isomer of folate and the primary form of folate in circulation," *i.e.*, L-5-MTHF. While it is true that L-5-MTHF is "the "primary biologically active isomer of folate and the primary form of folate in circulation," it is not true that Xolafin™ is L-5-MTHF.

64. D,L-5-MTHF (or 5-MTHF) is a different dietary ingredient from L-5-MTHF and has been separately listed with the FDA pursuant to a New Dietary Ingredient Notification submitted by General Nutrition Corporation ("GNC") in 1998.

65. The GNC New Dietary Ingredient Notification specifies the dietary ingredient D,L-5-MTHF is a diastereoisomeric mixture, which is composed of 50% each of the two diastereoisomers, the L-isomer and the D-isomer.

66. Merck's New Dietary Ingredient Notification specifies the dietary ingredient L-5-MTHF as, *inter alia*, containing less than 1.0% of the D-isomer. The dietary ingredient L-5-MTHF is therefore a substantially diastereoisomerically pure ingredient, whereas the dietary ingredient D,L-5-MTHF is a 1 to 1 diastereoisomeric mixture.

67. Upon information and belief, Brookstone has knowledge that its PNV-DHA, PNV and Folast products use the dietary ingredient D,L-5-MTHF and not the dietary ingredient L-5-MTHF.

68. Upon information and belief, through at least the PNV-DHA, PNV and Folast product labels, product inserts and marketing materials, which Brookstone has provided to the medical community, consuming public, the national pharmaceutical databases and others, Brookstone has falsely represented and continues to falsely represent that its PNV-DHA, PNV and Folast products uses the dietary ingredient L-5-MTHF.

69. Upon information and belief, Brookstone has falsely represented that its PNV-DHA, PNV and Folast products are pharmaceutically equivalent to and substitutable for Sciele's PRENATE DHA®, PRENATE ELITE® and Pamlab's METANX®, respectively, despite critical differences in their folate ingredients. Upon information and belief Brookstone has falsely represented that its PNV-DHA, PNV and Folast products are therapeutically equivalent to and substitutable for Sciele's PRENATE DHA®, PRENATE ELITE® and Pamlab's METANX®, despite the fact that no tests establishing therapeutic equivalency have been conducted. That is, Brookstone has represented that its PNV-DHA, PNV and Folast products are generic versions of Sciele's PRENATE DHA® and PRENATE ELITE® and Pamlab's METANX ® when, in fact, they are not.

Brookstone's False Advertising and Promotion

70. That Brookstone falsely advertises its products by describing the ingredient used as L-5-MTHF is readily apparent because Brookstone fails to follow standard chemical nomenclature conventions.

71. Specifically, to avoid consumer confusion, the source ingredients for folate must be described by their common or usual names. Furthermore, it is industry practice to use the name provided in a New Dietary Ingredient Notification ("NDI"), among other documents, as the common name of a dietary ingredient.

72. Here, Merck has submitted an NDI directed to the dietary ingredient L-5-MTHF and GNC has submitted an NDI directed to the dietary ingredient D,L-5-MTHF (or 5-MTHF).

73. Brookstone continues to falsely represent that the False Generics use the ingredient L-5-MTHF when they do not.

74. Upon information and belief, through at least its product labels, package inserts and marketing materials distributed to customers, potential customers, national

pharmaceutical databases and others, Brookstone has marketed the False Generics that contain the dietary ingredient D,L-5-MTHF as containing the dietary ingredient L-5-MTHF in an effort to induce pharmacists, physicians, customers, the public and the marketplace to believe that the products contain genuine L-5-MTHF, when they do not.

75. Brookstone is deliberately misrepresenting to pharmacists, physicians, consumers, the public and the marketplace that the False Generics are pharmaceutically equivalent to, including having the same efficacy and safety as, those products sold by Merck's customers, such as Sciele and Pamlab, when, in fact, the brand and the False Generic products are not pharmaceutically equivalent.

76. Through its marketing materials for its PNV-DHA, PNV and Folast products, Brookstone is also deliberately misrepresenting to pharmacists, physicians, consumers, the public and the marketplace that its PNV-DHA, PNV, and Folast products are therapeutically equivalent to Sciele's PRENATE DHA® and PRENATE ELITE®, and Pamlab's METANX®, when, in fact, upon information and belief, no tests to establish therapeutic equivalence of the False Generics to the branded products have been conducted.

77. Specifically, in advertising for discounts given to pharmacists, Brookstone states: "In establishing the AWP, as reported by Brookstone Pharmaceuticals LLC, the SWP for the branded therapeutically equivalent product is referenced, as it is listed in nationally recognized publications such as First Data Bank."

78. Moreover, through at least its product labels, package inserts and marketing materials, Brookstone induces national pharmaceutical drug databases to falsely advertise that the False Generics contain the dietary ingredient L-5-MTHF.

79. The therapeutic effects of such False Generics compared to products containing the dietary ingredient L-5-MTHF could be inferior. For example, the nutritionally

inactive D-diastereoisomer could compete with the uptake and activity of the L-diastereoisomer, among other things.

80. Any of the above results could expose the general public, including consumers in New York, to undesirable medical implications, especially considering these products are specifically prescribed for patient populations with severe folate needs.

81. The distribution and sale of the False Generics have and will continue to cause Merck to lose sales of its genuine L-5-MTHF to both existing Merck customers and to potential customers.

82. The distribution and sale of the False Generics also have and will continue to cause, Merck's customers, such as Sciele and Pamlab, to lose sales of PRENATE DHA®, PRENATE ELITE® and METANX®, as such sales are usurped by Brookstone as a result of its efforts to induce the national pharmaceutical databases to improperly list the False Generics as true generics when they are not.

83. The marketing of the False Generics as containing the dietary ingredient L-5-MTHF will tarnish the reputations of Merck, its customers and its L-5-MTHF product. It may also tarnish the reputation of products containing Merck's dietary ingredient L-5-MTHF.

COUNT I

FALSE ADVERTISING IN VIOLATION OF SECTION 43(a)(1)(B) OF THE LANHAM ACT, 15 U.S.C. § 1125(a)(1)(B)

84. Plaintiff incorporates herein and realleges, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 83 above, inclusive.

85. Defendant's product labels, package inserts, and marketing materials, which state that its False Generics incorporate the dietary ingredient or ingredient L-5-MTHF, are materially false statements that misrepresent the nature, characteristics and qualities of these products. These are material misrepresentations upon which at least the public, marketplace, pharmacists, customers or potential customers have, and will rely.

86. Upon information and belief, Defendant, by virtue of its false statements that the False Generics contain L-5-MTHF, when they do not, has also falsely represented that the False Generics are pharmaceutically equivalent to at least Sciele's PRENATE DHA® or PRENATE ELITE® or Pamlab's METANX®. Upon information and belief, Defendant has also falsely represented that its False Generics are therapeutically equivalent to Sciele's PRENATE DHA® or PRENATE ELITE®, or Pamlab's METANX®.

87. Defendant's actions, therefore, mislead and harm customers and consumers, among others, as well as damage Merck's sales, good name and reputation in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

88. Given Brookstone's knowledge that the False Generics contain the dietary ingredient or ingredient D,L-5-MTHF, and not the dietary ingredient or ingredient L-5-MTHF, and knowledge that no tests have been conducted establishing the therapeutic equivalence of the False Generics to the branded products, the aforesaid acts were undertaken willfully and deliberately and with the intention of causing confusion, mistake, or deception.

89. The aforesaid acts of Defendant have caused, and will continue to cause, damage to Plaintiff in an amount to be determined at trial.

90. The aforesaid acts of Defendant have caused, and unless restrained and enjoined by this Court, will continue to cause irreparable harm, loss, and injury to Plaintiff for which Plaintiff has no adequate remedy at law.

COUNT II

CONTRIBUTORY FALSE ADVERTISING IN VIOLATION OF SECTION 43(a)(1)(B) OF THE LANHAM ACT, 15 U.S.C. § 1125(a)(1)(B)

91. Plaintiff incorporates herein and realleges, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 90 above, inclusive.

92. Upon information and belief, Defendant has falsely told national pharmaceutical databases that its False Generics contain the dietary ingredient or ingredient L-5-MTHF and are therefore pharmaceutically equivalent to at least Sciele's PRENATE DHA® or PRENATE ELITE® or Pamlab's METANX®. Upon information and belief, Defendant has also falsely told national pharmaceutical databases that its False Generics are therapeutically equivalent to Sciele's PRENATE DHA® and PRENATE ELITE®, and Pamlab's METANX®.

93. Defendant induced the national pharmaceutical databases to engage in false advertising by describing the Brookstone False Generics as pharmaceutically equivalent to and substitutable for Sciele's PRENATE DHA® and PRENATE ELITE® and Pamlab's METANX®, which contain the dietary ingredient L-5-MTHF. Defendant also induced the national pharmaceutical databases to engage in false advertising by describing the False Generics as therapeutically equivalent and substitutable for Sciele's PRENATE DHA® and PRENATE ELITE® and Pamlab's METANX®, when no tests establishing therapeutic equivalence of the False Generics and the brand products have been conducted.

94. Defendant knew or had reason to know that the national pharmaceutical databases would engage in false advertising by describing the Brookstone False Generics as substitutable to the branded products; in other words, using the dietary ingredient L-5-MTHF. Defendant knew or had reason to know that the national pharmaceutical databases would engage in false advertising by describing Brookstone's False Generics as therapeutically equivalent to the branded products.

95. As a result, the national pharmaceutical databases have made and continue to make materially false statements that misrepresent the nature, characteristics and qualities of Brookstone's False Generics. These are material misrepresentations upon which at least the public, marketplace, pharmacists, customers or potential customers have and will rely.

Defendant's actions, therefore, cause the national pharmaceutical databases to mislead and harm consumers, among others, as well as damage Merck's and its customers' sales, good name and reputation in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

96. Given Brookstone's knowledge that its products incorporate the dietary ingredient or ingredient D,L-5-MTHF and not the dietary ingredient or ingredient L-5-MTHF, and knowledge that no tests establishing the therapeutic equivalence of the False Generics to the branded products have been conducted, the aforesaid acts were undertaken willfully and deliberately and with the intention of causing confusion, mistake, or deception.

97. The aforesaid acts of Defendant have caused, and will continue to cause, damage to Plaintiff in an amount to be determined at trial.

98. The aforesaid acts of Defendant have caused, and unless restrained and enjoined by this Court, will continue to cause irreparable harm, loss, and injury to Plaintiff for which Plaintiff has no adequate remedy at law.

COUNT III

FEDERAL UNFAIR COMPETITION IN VIOLATION OF SECTION 43(a)(1)(A) OF THE LANHAM ACT, 15 U.S.C. § 1125(a)(1)(A)

99. Plaintiff incorporates herein and realleges, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 98 above, inclusive.

100. Defendant's product labels, package inserts, and marketing materials, which state that its False Generics incorporate the dietary ingredient or ingredient L-5-MTHF and are therapeutically equivalent to the branded products, are materially false statements.

101. Such materially false statements have caused and are likely to continue to cause confusion, mistake, or deception as to the origin, sponsorship or approval of the folate ingredient in Brookstone's False Generics.

102. Brookstone, therefore, has willfully promoted its False Generics in interstate commerce so as to cause confusion or mistake among the public as to the origin, sponsorship or approval of the folate ingredient in Brookstone's False Generics, all to Brookstone's profit and the public's, Merck's and Merck's customers' damage.

103. Given Brookstone's knowledge that the False Generics use the dietary ingredient or ingredient D,L-5-MTHF and not the dietary ingredient or ingredient L-5-MTHF, and knowledge that no tests establishing the therapeutic equivalence of the False Generics to the branded products have been conducted, the aforesaid acts were undertaken willfully and deliberately.

104. The aforesaid acts of Brookstone constitute use of false descriptions and false representations in interstate commerce in violation of § 43(a)(1)(A) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(A).

105. The aforesaid acts of Brookstone have caused, and will continue to cause, damage to Plaintiff in an amount to be determined at trial.

106. The aforesaid acts of Brookstone have caused, and unless restrained and enjoined by this Court, will continue to cause irreparable harm, loss, and injury to Plaintiff for which Plaintiff has no adequate remedy at law.

COUNT IV

COMMON LAW UNFAIR COMPETITION

107. Plaintiff incorporates herein and realleges, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 106 above, inclusive.

108. Brookstone has made false statements to the marketplace, public and its customers and has mislabeled the Brookstone False Generics with the intent of deceiving and misleading the public as to the quality and nature of its product.

109. The aforesaid acts have enabled Brookstone to misappropriate the labors and expenditures of Merck in developing the market for the dietary ingredient L-5-MTHF.

110. Additionally, the aforesaid acts have caused, and are likely to continue to cause injury to the public and to Merck's and Merck's customers' sales, business reputation, and result in Brookstone unfairly competing with Merck.

111. Given Brookstone's knowledge that the False Generics use the dietary ingredient or ingredient D,L-5-MTHF and not the dietary ingredient or ingredient L-5-MTHF, and knowledge that no tests establishing the therapeutic equivalence of the False Generics to the branded products have been conducted, the aforesaid acts were undertaken willfully and deliberately.

112. The aforesaid acts of Defendant have caused, and will continue to cause, damage to Plaintiff in an amount to be determined at trial.

113. The aforesaid acts of Defendant have caused, and unless restrained and enjoined by this Court, will continue to cause irreparable harm, loss, and injury to Plaintiff for which Plaintiff has no adequate remedy at law.

COUNT V

DECEPTIVE TRADE PRACTICES IN VIOLATION OF N.Y. GEN. BUS. LAW § 349(h)

114. Plaintiff incorporates herein and realleges, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 113 above, inclusive.

115. Brookstone has been and is engaging in willful deceptive acts or practices in New York against Merck and the public in the conduct of its business through the following consumer-oriented acts: making false and misleading statements to national pharmaceutical databases; making false and misleading statements in at least its package inserts; making false and misleading commercial advertising or promotions; mislabeling its False Generics as containing the dietary ingredient or ingredient L-5-MTHF, which materially misrepresent the

nature, characteristics and qualities of the goods and services associated with Brookstone's False Generics; and making false and misleading statements in its marketing materials that the False Generics are therapeutically equivalent to the branded products. The aforesaid acts of Brookstone are in violation of N.Y. Gen. Bus. Law § 349(h).

116. The aforesaid misleading acts of Brookstone have additionally caused, and are likely to continue to cause injury to the public, including consumers in New York, and injury to Merck's and Merck's customers' sales and business reputation.

117. Brookstone's acts have caused, and unless restrained by this Court, will continue to cause, great and irreparable damage to the public and to Merck's and its customers' business and goodwill for which Merck and the public have no adequate remedy at law.

118. As a result of Brookstone's willful and intentional misconduct, Merck and the public are therefore entitled to appropriate relief as prayed for hereinafter, including preliminary and permanent injunctive relief.

119. Moreover, Brookstone's willful and knowing violation of Section 349(h) warrants treble damages and the recovery of attorneys' fees.

COUNT VI

FALSE ADVERTISING
IN VIOLATION OF N.Y. GEN. BUS. LAW § 350(e)(3)

120. Plaintiff incorporates herein and realleges, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 119 above, inclusive.

121. Brookstone has been and is engaging in false advertising in New York against Merck and the public in the conduct of its business through the following consumer-oriented acts: making false and misleading statements to national pharmaceutical databases; making false and misleading statements in at least its package inserts; making false and misleading commercial advertising or promotions; mislabeling its False Generics as containing the

dietary ingredient or ingredient L-5-MTHF, which materially misrepresent the nature, characteristics and qualities of the goods and services associated with Brookstone's False Generics; and making false and misleading statements in its marketing materials that the False Generics are therapeutically equivalent to the branded products. The aforesaid acts of Brookstone are in violation of N.Y. Gen. Bus. Law § 350(e)(3).

122. The aforesaid false statements of Brookstone have additionally caused, and are likely to continue to cause injury to the public, including consumers in New York, and injury to Merck's sales and business reputation.

123. Brookstone's acts have caused, and unless restrained by this Court, will continue to cause, great and irreparable damage to the public and to Merck's and its customers' business and goodwill for which Merck and the public have no adequate remedy at law.

124. As a result of Brookstone's willful and intentional misconduct, Merck and the public are therefore entitled to appropriate relief as prayed for hereinafter, including preliminary and permanent injunctive relief.

125. Moreover, Brookstone's willful and knowing violation of Section 350(e)(3) warrants treble damages and the recovery of attorneys' fees.

JURY DEMAND

Plaintiff demands a trial by jury of all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays for the following relief:

A. The Court enter judgment that Defendant, as a result of its willful, deliberate, and materially false statements regarding the quality and content of its products has engaged in: false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B); contributory false advertising in violation of Section 43(a)(1)(B) of the

Lanham Act, 15 U.S.C. § 1125(a)(1)(B); federal unfair competition in violation of Section 43(a)(1)(A) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(A); unfair competition in violation of New York common law; deceptive trade practices in violation of N.Y. Gen. Bus. Law § 349(h); and false advertising in violation of N.Y. Gen. Bus. Law § 350(e)(3).

B. The Court enter judgment finding that this is an exceptional case;

C. The Court issue preliminary and permanent injunctions ordering Defendant to, *inter alia*, immediately cease all distribution, sale and advertising of its products that contain or claim to contain 5-MTHF or L-5-MTHF, including but not limited to the PNV-DHA, PNV, and Folast products;

D. The Court order the delisting from the national pharmaceutical databases of Brookstone's products that contain or claim to contain 5-MTHF or L-5-MTHF, including but not limited to the PNV-DHA, PNV, and Folast products;

E. The Court order a recall of all of Defendant's products that contains or claim to contain 5-MTHF or L-5-MTHF, including but not limited to the PNV-DHA, PNV, and Folast products currently in the marketplace;

F. The Court order that Brookstone engage in a program of corrective advertising, satisfactory to Merck, to ameliorate the false and misleading information that Brookstone has promulgated;

G. The Court grant an award of damages in an amount sufficient to compensate Merck for injury it has sustained as a consequence of Defendant's unlawful acts;

H. The Court grant an award of treble damages;

I. The Court grant an award of punitive damages in an amount sufficient to punish and deter Defendant from engaging in further knowing acts of unfair competition;

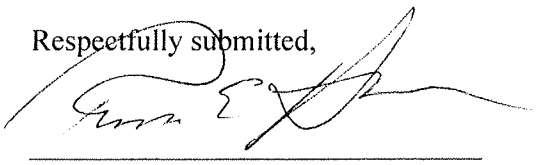
J. The Court grant the costs of this action and the reasonable attorneys' fees and other expenses of litigation Merck incurs in connection with this action;

K. The Court grant Plaintiff prejudgment interest and costs; and

L. The Court grant such other, different, and additional relief as the Court deems just and proper.

Dated: January 13, 2010

Respectfully submitted,



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Attorneys for Plaintiff Merck Eprova AG

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MERCK EPROVA AG,

Plaintiffs,

-vs.-

BROOKSTONE PHARMACEUTICALS, LLC a/k/a ACELLA PHARMACEUTICALS, LLC,

Defendant.

09 CV 9684 (RJS) (JCF)

AFFIDAVIT OF SERVICE

STATE OF NEW YORK)

COUNTY OF NEW YORK)

Alwina Oyewoleturner, being duly sworn, deposes and says that I am employed in the office of Alston & Bird LLP, attorneys for Plaintiff Merck Eprova AG, and that on January 13, 2010, I served a true copy of a First Amended Complaint by emailing and mailing a copy of the same via overnight delivery to the following counsel:

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Attorneys for Defendant Brookstone Pharmaceuticals, LLC a/k/a/ Acella Pharmaceuticals, LLC

Sworn to before me this 13th day of January 13, 2010.

Notary Public

YOLANDA SANCHEZ
Notary Public, State of New York
No. 01SA6157467
Qualified in Bronx County
Commission Expires Dec. 11, 2010